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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,021	02/05/2004	Stephen William Watson Michnick	Oddy 006	5538

7590 07/11/2005
Isaac A. Angres
2001 Jefferson Davis Highway
Suite 301
Arlington, VA 22202

EXAMINER

BRUSCA, JOHN S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/772,021

Applicant(s)

MICHNICK ET AL.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005 and 16 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 29-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30 and 31 is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-27, 29, 32-35 and 38 is/are rejected.
- 7) ☒ Claim(s) 13, 36, 37 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/017412.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of the specie of p53 fused to a reporter fragment, the specie of receptor tyrosine kinase cellular pathway, and the specie of receptor agonist drug category in the reply filed on 02 May 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

2. The abstract of the disclosure is objected to because it is too long. The amendment to the abstract filed 02 May 2005 is objected to due to excessive length. Correction is required. See MPEP § 608.01(b).

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

4. The objection to claims 16 and 35 in the Office action mailed 01 November 2004 is withdrawn in view of the amendment to the claims filed 16 May 2005.

Claim Rejections - 35 USC § 112

5. The rejection of claims 6, 9, 19, 20, and 31-35 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement in the Office action mailed 01 November 2004 is withdrawn in view of the amendment to the claims filed 16 May 2005.

6. The rejection of claims 13 and 31 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in the Office action mailed 01 November 2004.

Claim Rejections - 35 USC § 102

7. The rejection of claims 26-29, and 39 under 35 U.S.C. 102(b) as being anticipated by Johnsson et al. in the Office action mailed 01 November 2004 is withdrawn in view of the amendment to the claims filed 16 May 2005.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnsson et al.

The claims are drawn to expression vectors encoding fusion proteins comprising fragments of protein reporter molecules. In some embodiments the vector comprises a promoter,

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or the vector or vectors encodes two fusion proteins comprising fragments of protein reporter molecules.

Johnsson shows an assay of fusion protein reassociation in figure 1e. The assay utilizes fragments of ubiquitin that do not reassociate unless linked to protein domains that have high binding affinity. Upon binding, the ubiquitin fragments are brought into close association and cleave a portion of one of the ubiquitin fragments. The cleavage activity is measured by gel electrophoresis immunoblot analysis in figure 4. Johnsson et al. shows expression vectors comprising an inducible P_{CUP1} promoter that is operable linked to open reading frames that encode the two fusion proteins depicted in Figure 1.

Claim Rejections - 35 USC § 103

10. The rejection of claims 26, 36, and 37 under 35 U.S.C. 103(a) as being unpatentable over Johnsson et al. in view of Ko et al. in the Office action mailed 01 November 2004 is withdrawn in view of the amendment to the claims filed 16 May 2005.

Terminal Disclaimer

11. The terminal disclaimers filed on 02 May 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos: 6,294,330, 6,428,951, and 6,270,964, and copending U.S. Applications 10/856620, 10/724178, 10/353090, 10/154758, and 09/603885 have been reviewed and are accepted. The terminal disclaimer has been recorded.

Double Patenting

12. The provisional rejection of claims 1-6, 8-12, 14-29, and 35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 6, and 11-14

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of copending Application No. 10/856620 in the Office action mailed 01 November 2004 is withdrawn in view of the terminal disclaimer filed 02 May 2005.

13. The provisional rejection of claims 5-9, 11, 15, 17, 19, 20, 22, and 24-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 13, 14, and 16 of copending Application No. 10/724178 in the Office action mailed 01 November 2004 is withdrawn in view of the terminal disclaimer filed 02 May 2005.

14. The provisional rejection of claims 5-9, 11, 15, 17, 19, 20, 22, and 24-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 74, 77, 80, and 82 of copending Application No. 10/353090 in the Office action mailed 01 November 2004 is withdrawn in view of the terminal disclaimer filed 02 May 2005.

15. The provisional rejection of claims 5-9, 11, 15, 17-20, 22, and 24-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 59-70, and 73-80 of copending Application No. 10/154758 in the Office action mailed 01 November 2004 is withdrawn in view of the terminal disclaimer filed 02 May 2005.

16. The provisional rejection of claims 5-9, 11, 15, 17, 19, 20, 22, and 24-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 18, 19, and 20-33 of copending Application No. 09/603885 in the Office action mailed 01 November 2004 is withdrawn in view of the terminal disclaimer filed 02 May 2005.

17. The rejection of claims 5-9, 11, 15, 17-20, 22, and 24-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12-16,

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and 18 of U.S. Patent No. 6,428,951 in the Office action mailed 01 November 2004 is withdrawn in view of the terminal disclaimer filed 02 May 2005.

18. The rejection of claims 1-9, 11, 14, 15, 17-20, 22, and 24-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-64 of U.S.

Patent No. 6,294,330 in the Office action mailed 01 November 2004 is withdrawn in view of the terminal disclaimer filed 02 May 2005.

19. The rejection of claims 1-9, 11, 15, 17-20, 22, and 24-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-41 of U.S.

Patent No. 6,270,964 in the Office action mailed 01 November 2004 is withdrawn in view of the terminal disclaimer filed 02 May 2005.

20. The provisional rejection of claims 2 and 38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-5 of copending

Application No. 10/856620 in view of Panayotou et al. in the Office action mailed 01 November 2004 is withdrawn in view of the terminal disclaimer filed 02 May 2005.

21. The rejection of claims 2 and 38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4, and 13-22 of U.S. Patent No. 6,294,330

in view of Panayotou et al. in the Office action mailed 01 November 2004 is withdrawn in view of the terminal disclaimer filed 02 May 2005.

22. The rejection of claims 2 and 38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27 and 37 of U.S. Patent No. 6,270,964 in

view of Panayotou et al. in the Office action mailed 01 November 2004 is withdrawn in view of the terminal disclaimer filed 02 May 2005.

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23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

24. It is brought to the applicant's attention that the Declaration under 37 CFR 1.132 filed 02 May 2005 by Stephen William Watson Michnick is ineffective to overcome the rejections under 35 CFR 102(f) because it does not establish that the claimed subject matter in common with the cited patent or application was invented by the same inventive entity. In order to overcome the rejections under 35 USC 102(f) a revised declaration should be submitted that identifies the correct inventive entity for the commonly claimed subject matter that makes it clear that the inventive entity for the commonly claimed subject matter in both the instant application and the cited patent or application is identical.

25. The wording of the declaration filed 02 May 2005 appears to raise an issue of incorrect inventorship in the cited patent or application because it states that subject matter claimed in the cited patent or application was invented by an inventive entity that includes individuals not listed as inventors of the cited patent or application. The applicants are requested to address this apparent inconsistency in their response to this Office action.

26. The rejections under 35 U.S.C. § 102(f) listed below are repeated for reasons of record in the Office action mailed 01 November 2004.

27. Claims 1-6, 8-12, 14-27, 29, and 35 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

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The instant claims are anticipated by copending Application No. 10/856620, which has a different inventive entity than the instant application.

28. Claims 5-9, 11, 15, 17, 19, 20, 22, 24-27, and 29 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The instant claims are anticipated by copending Application No. 10/724178, which has a different inventive entity than the instant application.

29. Claims 5-9, 11, 15, 17, 19, 20, 22, 24-27, and 29 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The instant claims are anticipated by copending Application No. 10/353090, which has a different inventive entity than the instant application.

30. Claims 5-9, 11, 15, 17-20, 22, 24-27, and 29 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The instant claims are anticipated by copending Application No. 10/154758, which has a different inventive entity than the instant application.

31. Claims 5-9, 11, 15, 17, 19, 20, 22, 24-27, and 29 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The instant claims are anticipated by copending Application No. 09/603885, which has a different inventive entity than the instant application.

32. Claims 5-9, 11, 15, 17-20, 22, 24-27, and 29 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The instant claims are anticipated by U.S. Patent No. 6,428,951, which has a different inventive entity than the instant application.

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33. Claims 1-9, 11, 14, 15, 17-20, 22, 24-27, and 29 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The instant claims are anticipated by U.S. Patent No. 6,294,330, which has a different inventive entity than the instant application.

34. Claims 1-9, 11, 15, 17-20, 22, 24-27, and 29 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The instant claims are anticipated by U.S. Patent No. 6,270,964, which has a different inventive entity than the instant application.

35. It is brought to the applicant's attention that the statement in pages 19-20 in the response filed 02 May 2005 that copending Application No. 10/856620 and U.S. Patent No. 6,294,330 are commonly owned does not serve to overcome a rejection under 35 U.S.C. § 103 because the exclusion of prior art under 35 U.S.C. § 103(c) requires that the instant and cited applications and patents be commonly owned **at the time the invention was made**. Absent a clear statement in the instant application file by the applicants that the rejections detailed below are precluded due to common ownership at the time the invention was made, the rejections will be maintained.

36. Claims 2 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over copending Application No. 10/856620 (which qualifies as prior art under 35 U.S.C. § 102(f)) in view of Panayotou.

The claims are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a receptor tyrosine kinase pathway.

Claims 2-5 of Application No. 10/856620 are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a cellular protein. Claims

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2-5 of Application No. 10/856620 do not show use of protein complementation assays to study a receptor tyrosine kinase pathway.

Panayotou et al. reviews receptor tyrosine kinases. Panayotou et al. shows on pages 172-174 and figure 2 that many receptor tyrosine kinases bind a variety of cellular proteins after activation of the receptor tyrosine kinase, and that such binding is essential for effecting the cell signal of extracellular ligand binding to the receptor.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assays of claims 2-5 of Application No. 10/856620 by use of a receptor tyrosine kinase protein linked to a reporter molecule because such a fusion protein would allow for further study of binding to the receptor tyrosine kinase by other proteins.

37. Claims 2 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,294,330 (which qualifies as prior art under 35 U.S.C. § 102(f)) in view of Panayotou.

The claims are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a receptor tyrosine kinase pathway.

Claims 3, 4, and 13-22 of U.S. Patent No. 6,294,330 are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a cellular receptor protein. Claims 3, 4, and 13-22 of U.S. Patent No. 6,294,330 do not show use of protein complementation assays to study a receptor tyrosine kinase pathway.

Panayotou et al. reviews receptor tyrosine kinases. Panayotou et al. shows on pages 172-174 and figure 2 that many receptor tyrosine kinases bind a variety of cellular proteins after

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activation of the receptor tyrosine kinase, and that such binding is essential for effecting the cell signal of extracellular ligand binding to the receptor.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assays of claims 3, 4, and 13-22 of U.S. Patent No. 6,294,330 by use of a receptor tyrosine kinase protein linked to a reporter molecule because such a fusion protein would allow for further study of binding to the receptor tyrosine kinase by other proteins.

38. Claims 2 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,270,964 (which qualifies as prior art under 35 U.S.C. § 102(f)) in view of Panayotou.

The claims are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a receptor tyrosine kinase pathway.

Claims 27 and 37 of U.S. Patent No. 6,270,964 are drawn to a method of using a protein complementation assay to study the effect of a compound on a cellular protein. Claims 27 and 37 of U.S. Patent No. 6,270,964 do not show use of protein complementation assays to study a receptor tyrosine kinase pathway.

Panayotou et al. reviews receptor tyrosine kinases. Panayotou et al. shows on pages 172-174 and figure 2 that many receptor tyrosine kinases bind a variety of cellular proteins after activation of the receptor tyrosine kinase, and that such binding is essential for effecting the cell signal of extracellular ligand binding to the receptor.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assays of claims 27 and 37 of U.S. Patent No. 6,270,964 by

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use of a receptor tyrosine kinase protein linked to a reporter molecule because such a fusion protein would allow for further study of binding to the receptor tyrosine kinase by other proteins.

Allowable Subject Matter

39. Claims 13, 36, 37, and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

40. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

41. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is

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(866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

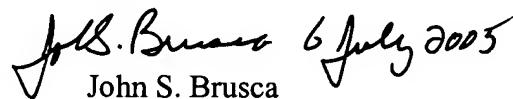
For all other customer support, please call the USPTO Call Center at (800) 786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD. can be reached on 571 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 6 July 2005

John S. Brusca
Primary Examiner
Art Unit 1631

jsb